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Claim 61 - The method of 60 including forming a closeable portal in the bag.

Claim 62 - The method of 61 including filling the bag with a thermolabile biological fluid and freezing the fluid in the bag.

REMARKS

The Office Action dated July 5, 2001, has been received and its contents carefully noted. With respect to the requirement for election and restriction between groups I, II, III and IV, applicant hereby provisionally elects group II, consisting of claims 19-23. Undersigned has included new claims 56-62 in response to the Examiner's Action. Applicant traverses the election requirement of all groups for a multiplicity of reasons.

Specifically, it is believed that claims 1-5, 11-13, 28-32, and 45-55 are so closely related to the elected claims that they should remain in the same application to preserve unity of the invention and thus avoid any possibility of the charge of double patenting arising at some later date. It is typically improper for process and apparatus claims involving exactly the same inventive concept and evidencing complete "uniting of invention" to be divided. *Steinmetz v. Allen*, 192 U.S. 543, 48 L.Ed. 555 (1904). All of the above-identified claims are directed to solving the problem of bag breakage and providing a bag of substantively uniform thickness. This is done by the mold, method, product by process and apparatus. As a result of this system (comprised in its entirety) the applicant has provided more reliable, efficient bags to contain thermolabile and/or cellular biological substances and formed such that they can withstand stresses at extremely cold, cryogenic

temperatures, reduce heat invasion from a higher ambient temperature into a plurality of such bags placed together, reduce storage space required for a plurality of such bags, and provide a thin and substantially constant cross-section for the bag so that the rate of heat transfer into and out of the bag is substantially homogenous throughout the contents of the bag *thereby providing an improved means of protecting the viability of living cells during freezing and thawing*. The statutory requirement under 35 U.S.C. §121 that there be both independence and distinction between the inventions has not been met. It has not been shown why the claims should be considered independently as required by the language of §121 and 37 C.F.R. §1.141(b). Therefore, this restriction requirement should be withdrawn.

More particularly, the Examiner generally asserts that groups I, II, III and IV are distinct inventions. However, undersigned points out the following additional requirements that the Examiner must meet to compel a restriction. In particular, MPEP §803 requires that there must also be a serious burden on the Examiner if restriction is required. Undersigned does not see any enunciation of such burden in the Examiner's restriction requirement. Furthermore, it is undersigned's contention that, to the contrary, the burden would be greater on the Examiner if restriction is required. That is, as all of the claims are closely related, solving the same problem, certain efficiencies would be achieved by the Examiner examining all groups simultaneously. Splitting the examination, as the Examiner is now requiring, will actually double this or another Examiner's work in the long run.

The Examiner had contended that the inventions of groups I, II, III and IV are distinct from each other in that other molding techniques could be used or the bag could have a different shape. However, the Examiner has offered no explanation as

to how he reached this conclusion and instead has engaged in mere speculation to the point of eviscerating the invention.

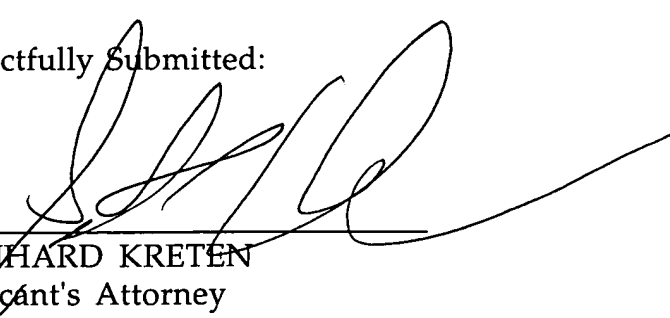
For all of the foregoing reasons, the Examiner is respectfully requested to withdraw the restriction requirement between groups I, II, III and IV. Applicant still reserves the right to file a divisional application for the non-elected subject matter and does not waive any right therefore or abandon such subject matter.

The Examiner is respectfully requested to note that the Office Action to which this Election and Preliminary Amendment responds was mailed on July 5, 2001, thereby requiring a response on August 5, 2001. August 5, 2001 was a Sunday. Therefore this Election and Preliminary Amendment is timely filed on Monday August 6, 2001

In view of the foregoing, the Examiner is respectfully requested to reconsider the position taken in the last Office Action acting favorably hereon by removing this restriction requirement. If, upon further consideration, the Examiner believes that further issues remain outstanding or new ones have been generated, please call undersigned in order to expeditiously resolve same.

Dated: August 6, 2001

Respectfully Submitted:



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